

U.S. Patent Application Serial No. 10/541,746  
Amendment filed June 7, 2010  
Reply to OA dated March 8, 2010

### **REMARKS**

Claims 1, 2, 4, 6 and 8-37 are pending in this application. Claims 1, 19 and 37 are amended herein. Upon entry of this amendment, claims 1, 2, 4, 6 and 8-37 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is detailed below.

**Claims 1-2, 4, 6 and 8-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415); an English machine translation of Katagiri et al. (JP 06-214197) was used. (Office action page 3)**

**Claims 19-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415); an English machine translation of Katagiri et al. (JP 06-214197) was used. (Office action page 5)**

**Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Valiant, JR. et al. (US 2002/0102415). For the purpose of examination, Baba**

U.S. Patent Application Serial No. 10/541,746  
Amendment filed June 7, 2010  
Reply to OA dated March 8, 2010

**et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415).**  
(Office action page 7)

**Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Hayashi et al. (US 6,503,632). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 8)**

**Claims 29-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Walther et al. (US 6,379,004). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action pages 8-9)**

**Claims 31-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Turek et al. (US 2002/0137811). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 9)**

**Claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 19 above, and further in view of Niwa et al. (US 5,516,467). For the purpose of examination, Baba et al. (U.S.**

U.S. Patent Application Serial No. 10/541,746  
Amendment filed June 7, 2010  
Reply to OA dated March 8, 2010

6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action page 10)

**Claim 37 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197). For the purpose of examination, Baba et al. (U.S. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415); an English machine translation of Katagiri et al. (JP 06-214197) was used. (Office action page 11)**

Reconsideration of the rejections is respectfully requested in view of the amendments to claims 1, 19 and 37. The amendment to recite a limitation on oxygen permeability coefficient (Dk) is supported by Example 25 in Table 13 on page 68 of the specification. The limitation on the water content of the ocular lens material is supported by page 38, lines 1-3, of the specification.

Applicant generally maintains the previously made arguments against these rejections. In addition, the present amendments to the claims further distinguish the claims from the cited references. These limitations, added to independent claims 1, 19 and 37, are present in all of the pending claims, and the following arguments are applicable to all of the rejections.

Regarding the Oxygen permeability (Dk)

The target of the copolymerization with N-MMP in Shibata et al. is an alkyl acrylate or an alkyl metacrylate and each of them is added for the purpose of increasing the intensity to lens material (column 2, line 25-26). Shibata does not provide a specific reason for copolymerizing N-

MMP with silicone compound, and in particular, does not provide the reason of the present invention.

In the presently amended claims, the Dk value of the optical lens material obtained by the present invention becomes not less than 51. However, the Dk value of the optical lens material obtained by Shibata et al. becomes absolutely lower: 23-43.

		present invention	Shibata et al.
components	essential hydrophobic component	polydimethylsiloxane macromer (A)	-
	essential hydrophiric component	pyrrolidone derivative (B)	N-MMP, N-VP
	other component	silicone containing (meth)acrylate (C)	alkyl (meth)acrylate
		N-substituted acrylamide	
Dk		$51 \leq$	23 to 43
Water content		32-55	$55.8 \leq$

Further, a silicone including (metha) acrylate, which is represented by B compound in Katagiri et al., corresponds to the compound (C) of the present invention and tris(trimethylsiloxy)silylpropyl (meth)acrylate is exemplified in the present invention and Katagiri et al. However, component (A) of the present invention, which has a polydimethylsiloxane structure, is not disclosed or suggested in Katagiri et al. As is shown in the following Table, Dk of the ocular lens material of the present invention which exists together with component (A), which has polydimethylsiloxane structure, becomes higher, more specifically not less than 51, while Dk of the ocular lens material of Katagiri et al. becomes lower, that is, less than or equal to 35.

		present invention	Katagiri et al.
components	essential hydrophobic component	polydimethylsiloxane macromer (A)	silicone containing (meth)acrylate (corresponds to component (C))
	essential hydrophiric component	pyrrolidone derivative (B)	N-MMP (one of component (B))
	other component	silicone containing (meth)acrylate (C)	DMAA (one of component (D))
		N-substituted acrylamide	
Dk		51≤	35≥
Water content		32-55	37-58

Although it is well known that silicone-containing component adds high oxygen permeability to the ocular lens material, it is an unexpected result that a component which has polydimethylsiloxane structure is superior to silicone-containing (meth)acrylate in view of increasing oxygen permeability. This result may be seen by comparing the results of Example 17 and Comparative Example 5 of the present specification. That is, in Example 17, 50 parts by weight of components (A) and (C) are used as a silicone component. On the other hand, in Comparative Example 5, the same weight (50 parts by weight) of component (C) as a silicone component and MMA are used. The result of Dk of Comparative Example 5 becomes lower than the result of Example 17 (more specifically, the results of Dk are 53 and 31, respectively (please see TABLEs 11 and 12)). These results are apparently showing that polydimethylsiloxane macromer component (A) is useful for increasing oxygen permeability.

Further, component (A), which has a polydimethylsiloxane structure, does not have good compatibility with other compounds which have high hydrophilic property like component (B) of

the present invention because of its hydrophobic property (please see Comparative Examples 4 and 5 of the present invention). Therefore, one of skill in the art, based on Katagiri et al., would predict that a lens polymer would become cloudy and it is not to be used as an adequate ocular lens material.

In Katagiri et al., the amount of silicone component for adding oxygen permeability to the ocular lens material is not more than 30% by weight at most. On the other hand, the amount of silicone component becomes 60% by weight. The reason why the amount of silicone component to the ocular lens of the present invention becomes larger is presumed to be an effect of existence of urethane bond which is included in the structure of component (A). The urethane bond included in component (A) is presumed to have an effect for increasing compatibility with another component.

In conclusion, one of skill in the art would not select the components including component (A), and the effect of increasing oxygen permeability, as stated above, is a completely unexpected result. The ocular lens material of Claim 1 is uniformly transparent, it is suitable for an ocular lens, it has reasonably high oxygen permeability and it is not suggested by the cited references.

Regarding reducing a residual monomer

Baba et al. discloses that a contact lens which has superior surface wettability and mechanical property is obtained by exactly controlling the amount of monomer and crosslinking agent for the purpose of preparing a silicone hydrogel lens which essentially contains N-VP.

Turning to the present invention, it can decrease the residual monomer drastically with keeping properties of N-VP such as superior hydrophilic property and wettability for the purpose of

make the same silicone hydrogel lens by using a N-MMP as an alternate with N-VP (please see Table 1-3, Example 1, Table 6-7, 11-12, Example 17, and Comparative Examples 1 and 2 of the present invention).

For reference, the following Tables compare the results of Examples 1 and 17 with Comparative Examples 1 and 2, respectively:

	Example 1	Comparative Example 1 corresponds to Baba et al.
monomer residual rate (%, based on total weight)	0.5	2.6
TOC aging change (ppmC, 14th day after sterilization)	4.8	11.8

	Example 17	Comparative Example 2 corresponds to Baba et al.
composition		
TRIS	25	25
macromonomer A	25	25
DMAA	12.5	12.5
N-MMP	37.5	-
NVP	-	37.5
monomer residual rate (%)	2.3	4
feeling test	A	A
contact angle	22	22
tensile modulus (MPa)	0.23	0.47

The Examiner states the above properties are easily predictable from Shibata et al. and Baba et al. Although Shibata et al. discloses superior copolymerizability between N-MMP and alkyl metacrylate, there is no specific Example in Shibata et al. about good copolymerizability or the elution amount of polymer. The data in the above Table clearly confirm that the amount of elution of polymer in the system of using N-VP (comparative Ex. 1) is larger than the system of using 1,3-MMP (Ex. 1). This result means that it is very important to reduce the amount of elution of unpolymerized polymer or oligomer from a finished contact lens (in other words, achieving low TOC value) to prepare a high safety ocular lens not only to reduce the amount of elution of unpolymerized monomer.

In this manner, the effects of simplifying the step of elution treatment to decrease the residual monomer, to reduce the quantity of polymer elution after the sterilization and to obtain a contact lens which has high safety property are industry-applicable and beneficial effects.

For the purpose of making a silicone hydrogel lens, the fact that the above effects in manufacturing occur as a result of using a specific combination of monomers, that is silicone macromer (A) and specific kinds of N-MMP (B), is not disclosed or suggested by Baba et al.

Further, the optical lens material obtained by the present invention has excellent lubricity/easy lubricating property and it is excellent in surface wettability. These properties are clearly understood by comparing Example 17 and Comparative Example 2. The results of feeling test and Contact angle which become reference marks of lubricity/easy lubricating property are same level but the result of tensile modulus which is reference mark of flexibility of the present invention



U.S. Patent Application Serial No. **10/541,746**  
Amendment filed June 7, 2010  
Reply to OA dated March 8, 2010

becomes absolutely lower than Baba et al. It is clear that the optical lens material of the present invention can provide the contact lens which has high safety and good wearing feeling.

As shown in the above Tables, the superior effects of the present invention are never obtained by combining components of Examples of Baba et al. Considering all the factors together, the contact lens material which has high safety ability, superior surface property and mechanical property with low quantity of residual monomer is obtained by using specific kinds of N-MMP as an alternative with N-VP, and it is not suggested by any references. Therefore, these effects are made known by the present invention for the first time and these effects are unexpected results from Shibata et al. and Baba et al. In particular, the mechanical property, which strongly relates to patient comfort of the ocular lens, is not predictable from Shibata et al. and Baba et al. and the effect of improving the mechanical property is newly shown by the present invention.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

U.S. Patent Application Serial No. **10/541,746**  
Amendment filed June 7, 2010  
Reply to OA dated March 8, 2010

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP



Daniel A. Geselowitz, Ph.D.

Agent for Applicants

Reg. No. 42,573

DAG/xl

Atty. Docket No. **050443**  
Suite 400  
1420 K Street, N.W.  
Washington, D.C. 20005  
(202) 659-2930



**23850**

PATENT & TRADEMARK OFFICE

H:\050\050443\Amendment in re OA of 03-08-10